IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, AND THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, WISCONSIN, AND THE DISTRICT OF COLUMBIA ex rel. DANIEL COYNE, M.D., Plaintiffs and Relator, v. AMGEN, INC., Defendant.	No. 12-cv-03881 (Feuerstein, J.) (Lindsay, M.J.) JURY TRIAL DEMANDED

FIRST AMENDED QUI TAM COMPLAINT

Relator, Daniel W. Coyne, M.D., by his undersigned attorneys, on behalf of the United States of America, the District of Columbia, and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin, states the following as

his First Amended Complaint ("FAC") based upon his non-public, direct, and independent knowledge:

I. BACKGROUND

1. Relator brings this action on behalf of the United States of America, the District of Columbia, and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin, to recover compensatory damages, treble damages, and civil penalties pursuant to the False Claims Act, 31 U.S.C. § 3729 et seq. and following false claims acts: the District of Columbia False Claims Act (DC ST § 2-308.03 et seq.); the California False Claims Act, (Cal. Gov't Code §§ 12650-12655); the Colorado Medicaid False Claims Act, (Col. Rev. Stat. § 25.5-1-104 et seq.); the Connecticut False Claims Act, (Chapter 319v, Sec. 17b-301 et seq.); the Delaware False Claims and Reporting Act (6 Del. C. § 1201 et seq.); the Florida False Claims Act (Fla. Stat. § 68.081 et seq.); the Georgia Medicaid False Claims Act (O.C.G.A. § 49-4-169 et seq.); the Hawaii False Claims Act (H.R.S § 661-21 and H.R.S. 46-171 et seq.); the Illinois Whistleblower and Reward Protection Act (740 I.L.C.S. § 175/1 et seq.); the Indiana False Claims Act (Burns Ind. Code Ann. § 5-11-5.5-1 et seq.); the Iowa Medicaid False Claims Act, (§ 685.1 et seq.); the Louisiana Medical Assistance Programs Integrity Law (La. R.S. § 46:437.2 et seq.); the Maryland False Health Claims Act of 2010 (Subtitle 6, False Claims Against State Health Plans and State Health Programs, § 2-601 et seq.); the Massachusetts False Claims Act (M.G.L.A. 12 § 5b et seq.); the Michigan Medicaid False Claims Act (M.C.L. § 400.607 et seq.); the Minnesota False Claims Act (Minn. Stat. § 15C.01 et seq.); the

Montana False Claims Act (Mont. Code Ann. § 17-8-401 et seq); the Nevada False Claims Act (N.R.S. § 357.010 et seq.); the New Hampshire False Claims Act (R.S.A. § 167:61-a); the New Jersey False Claims Act (New Jersey Statutes 2A:32C-1 et seq.); the New Mexico Fraud Against Taxpayers Act (N.M. Stat. Ann. § 44-9-1); the New York False Claims Act (N.Y. C.L.S. St. Fin. § 187 et seq.); the North Carolina False Claims Act, (N.C. Gen. Stat §§ 1-605 et seq.); the Oklahoma Medicaid False Claims Act (56 Okl. St. § 1005 et seq. and 2007 OK. A.L.S. 137); the State False Claims Act of Rhode Island (R.I. Gen. Laws § 91.1-3); the Tennessee Medicaid False Claims Act (T.C.A. § 71-5-181 et seq.); the Texas Medicaid Fraud Prevention Law (Tex. Hum. Res. Code § 36.002 et seq); the Virginia Fraud Against Taxpayers Act (Va. Code Ann. § 8.01-216.1 et seq.); the Washington Medicaid Fraud False Claims Act, RCWA 74.66.140 et seq., and the Wisconsin False Claims for Medical Assistance Act (Updated 05-06 Wis. Stats. § 20.931 et seq.). The aforementioned states and the District of Columbia shall hereinafter be collectively referred to as the "Plaintiff States." The United States of America and the Plaintiff States shall hereinafter be collectively referred to as the "Government Plaintiffs."

II. PARTIES

2. Defendant Amgen, Inc. (“Amgen”) is a publicly traded multinational biopharmaceutical company headquartered in Thousand Oaks, California. Amgen discovers, develops, manufactures, and distributes biopharmaceuticals dealing with inflammation, metabolic disorders, osteoporosis, neurology, oncology, and hematology. In 1989, Amgen received approval for epoetin alfa (“epoetin”) from the Food and Drug Administration (“FDA”) for the treatment of anemia. Epoetin, sold by Amgen under the brand name Epogen, is a synthetically produced hormone that promotes red blood cell production.

3. Beginning in 1996 and continuing through at least 2010, Amgen caused the Government Plaintiffs to pay for Epogen that Amgen knew was not reasonable and necessary for the diagnosis or treatment of illness or injury. Specifically, Amgen caused the Government Plaintiffs to pay for prescriptions of Epogen to target hemoglobin levels of patients on dialysis with heart disease to above 11 grams per deciliter (g/dL) of whole blood even though Amgen had actual knowledge during the entire period between 1996 and 2010 that targeting hemoglobin levels in this patient class to above 11 g/dL was not reasonable and necessary for the diagnosis or treatment of illness or injury and did not provide any therapeutic or diagnostic benefit. Amgen's unlawful conduct described in this FAC was intended to, and did, cause the submission of millions of false claims for Epogen that were ineligible for reimbursement to healthcare programs, such as Medicare, Medicaid, and Tricare, funded by the Government Plaintiffs.

4. Relator, Daniel W. Coyne, M.D. ("Coyne"), is a former paid speaker for Amgen and in that capacity was privy to non-public documents that led him to discover Amgen's fraud. Coyne resides in St. Louis, Missouri. He is a Professor of Medicine at Washington University School of Medicine and specializes in renal diseases. He received his medical degree from Case Western Reserve, completed a residency at Emory University, and completed a fellowship at Washington University in St. Louis. Coyne discovered Amgen's fraud and brought it to the attention of the federal government. As the result of Coyne's efforts taken over several years, CMS and other government funded healthcare programs changed the way they reimburse for Epogen and the FDA changed the label of Epogen to reflect the true risks and benefits of Epogen.

III. JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

6. This Court also has jurisdiction over the subject matter of this action pursuant to 31 U.S.C. § 3730(e) of the United States False Claims Act ("FCA") because there has been no statutorily relevant public disclosure of the allegations or transactions in this FAC.

7. If there were a public disclosure, then Coyne is an original source. Specifically, prior to the public disclosure, Coyne voluntarily disclosed to the Government the information on which allegations or transactions in the claims in this FAC are based. Additionally, if there were a public disclosure, Coyne has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and Coyne voluntarily provided his knowledge to the Government before commencement of this action.

8. On or around June 29, 2012, Coyne provided to the Attorney General of the United States and the attorneys general and other proper officials of the Government Plaintiffs a disclosure statement summarizing and supported by all known material evidence in accordance with the provisions of 31 U.S.C. § 3730(b)(2) and applicable state law. Three weeks later, on July 19, 2012, the Washington Post ran a major exposé on Amgen's fraud and noted that none of the fraud would have become public if not for Coyne's actions.

9. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a).

10. This Court has personal jurisdiction over Amgen and venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because those sections authorize nationwide service of process and because Amgen has minimum contacts with the United States. Further, Amgen can be found in, resides, and transacts business in this judicial district.

IV. LEGAL FRAMEWORK

A. Liability – Establishing Provisions of the FCA

11. Congress enacted the FCA in 1863 to collect money obtained through fraud and curb fraud during the Civil War. Congress significantly altered the FCA in 1986 through enactment of the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress amended the law to ensure that individuals who provided information to the government about fraud on the government were incentivized to file suit on behalf of the United States, to strengthen the government's ability to recover fraudulently obtained funds, and to deter corporations from engaging in fraud on the government. In 2009, Congress again amended the FCA, this time through the Fraud Enforcement and Recovery Act ("FERA"). In 2010, Congress amended the FCA through the Affordable Care Act ("ACA"). The purpose of these acts was to enable the government and relators to more easily pursue claims of fraud against the government and limit defenses that were undermining the purpose of the FCA.

12. The FCA imposes liability on any person or corporation that knowingly presents or causes to be presented a false or fraudulent claim to the United States government for payment or approval, 31 U.S.C. § 3729(a)(1)(A); any person or

corporation that makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the United States government, 31 U.S.C. § 3729(a)(1)(B); any person or corporation that conspires to defraud the Government by getting a false or fraudulent claim allowed or paid, 31 U.S.C. § 3729(a)(1)(C); and/or any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the United States government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the United States government. 31 U.S.C. § 3729(a)(1)(G).

13. Proof of specific intent to defraud the government is not required to establish a violation of the FCA. Rather, knowing and knowingly within the meaning of the FCA mean that a person has either actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information.

14. The FCA provides that any person who violates any of the aforementioned provisions is liable not just for return of all payments falsely made, but also for civil penalties of up to $11,000 per false claim, and for three times the amount of the damages sustained by the government.

15. The Plaintiff States have enacted qui tam laws analogous to the federal FCA that precisely mirror its language. The same unlawful conduct of Defendant in marketing Epogen alleged in this FAC that gives rise to its liability under the FCA likewise gives rise to its liability under the analogous laws of the Plaintiff States.

B. Government Health Care Programs

16. In 1965, Congress enacted Title XVIII of the Social Security Act (known as "Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care. The programs are overseen by the Center for Medicare and Medicaid Services ("CMS"). Entitlement to Medicare is based on age, disability, or affliction with certain diseases. See 42 U.S.C. §§1395 to 1395ccc. Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, effective January 1, 2006, Medicare Part D took effect, extending prescription drug coverage to all Medicare eligible persons who choose to participate in Part D.

17. In 1965, the federal government also enacted the Medicaid program. Medicaid is a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of the total amount expended as medical assistance under the State plan. See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as Federal Financial Participation ("FFP").

18. TRICARE Management Activity ("TRICARE"), formerly known as CHAMPUS, is a program of the Department of Defense that helps pay for covered civilian health care obtained by military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. 10 U.S.C. §§ 1079, 1086; 32

C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims.

19. The federal government, through its Departments of Defense and Veterans Affairs, maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non-profit disproportionate share hospitals ("DSH"). See generally 38 U.S.C. § 8126.

20. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries.

21. Together these programs described in paragraphs 16 through 20, and any other government funded healthcare programs, shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs."

22. Under the Medicare Act, 42 U.S.C. § 1395y(a)(1)(A), there is an express fundamental condition of payment: "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury." This condition links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary." The other Federal Health Care Programs restrict coverage under the same principle.

23. Hospitals and other inpatient facilities participating in the Medicare, Medicaid, and other Federal Health Care programs are required to file annual cost reports with the appropriate agencies. When a provider submits a Medicaid cost report, which includes requests for payment for pharmaceuticals that were not reasonable, and necessary, the claims for those expenses are legally false claims.

C. Government Payment for Dialysis and Epogen

24. The 1972 amendments to the Social Security Act extended Medicare benefits to people with end state renal disease ("ESRD") who are eligible for Social Security benefits, including those under age 65 years. ESRD patients entitled to Medicare due to kidney disease alone have the same benefits as other Medicare patients.

25. Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). Dialysis replaces the filtering function of the kidneys when they fail.

26. Most dialysis patients—more than 355,000 patients in 2010—are covered by fee-for-service (FFS) Medicare as the primary or secondary payer. About 47 percent of patients are dually eligible for Medicare and Medicaid. Between 1996 and 2010, Medicare paid for dialysis treatment as a bundle of services, including nursing, dietary counseling and other clinical services, dialysis equipment and supplies, social services, and certain laboratory tests and drugs.

27. In addition, Medicare made an add-on payment for certain drugs, including Epogen, provided to dialysis patients. Because Medicare's reimbursement rates for Epogen exceeded providers' acquisition costs for the drug, this add-on payment reimbursement scheme incentivized providers to administer Epogen to dialysis patients.

28. In 2010, more than 355,000 ESRD beneficiaries on dialysis were covered under FFS Medicare and received dialysis from about 5,500 ESRD facilities. In that year, Medicare expenditures for outpatient dialysis services, including separately billable drugs administered to dialysis patients, such as Epogen, were $9.5 billion.

29. Since 1989, Amgen has sold more than $37 billion worth of Epogen to treat America dialysis patients, a significant amount of which was paid for by Government Plaintiffs to target hemoglobin levels of dialysis patients on dialysis with heart disease to above 11 g/dL of whole blood.

V. AMGEN'S FOURTEEN-YEAR, MULTIBILLION DOLLAR FRAUD ON THE TAXPAYERS

A. Development and Approval of Epogen

30. Formed in 1980 by a group of scientists and venture capitalists, Amgen has grown from a struggling biotech startup to a Fortune 500 company. The foundational factor driving its growth was the development of an erythropoietin stimulating agent called epoetin alfa – a synthetically produced hormone that promotes red blood cell production. Epoetin is a protein produced in the kidneys that causes the body to produce oxygen-carrying red blood cells. After isolating epoetin in the mid 1980s, Amgen spliced the human epoetin gene into hamster ovary cells, which were grown in culture and could churn out large quantities of the protein to use as a drug.

31. Nearly all dialysis patients have anemia because diseased kidneys typically do not produce sufficient amounts of a hormone that stimulates production of red blood cells, leading to the development of anemia. Epoetin increases red blood cell ("RBC") production and hemoglobin (Hgb) levels. There is a direct relationship between the amount of epoetin administered and the hemoglobin content measured as grams per

deciliter (g/dL) of whole blood. That is to say, higher doses of epoetin yield higher levels of hemoglobin.

32. During the mid 1980's, Amgen contracted with Johnson & Johnson ("J&J") in an effort to secure financial and technical assistance towards completing Epoetin's development and FDA approval. Amgen sold J&J the right to market epoetin in the United States for all non-dialysis uses. Amgen retained exclusive rights to the U.S. dialysis market. Outside the United States, except for China and Japan, J&J also had the exclusive rights to market epoetin for all uses.

33. By 1986, epoetin was undergoing human testing and was targeted for people with kidney disease on dialysis. One year later, Amgen had filed epoetin for FDA approval.

34. On June 1, 1989, the FDA approved epoetin for the treatment of anemia in kidney dialysis patients. Amgen began marketing epoetin under the brand name Epogen immediately upon FDA approval. In fact, the first day after FDA approval, Amgen had already shipped its first batch of Epogen to UCLA Medical Center. By the end of June of 1989, Amgen sold nearly $17 million worth of Epogen.

35. The Food and Drug Administration ("FDA") set the target for epoetin - increased hemoglobin levels in anemic patients at 10-11 g/dL, which is to say that the FDA determined epoetin should be used to raise the hemoglobin levels in anemia patients to between 10 and 11 grams of hemoglobin per deciliter of whole blood. FDA increased this target just a few years later to 10-12 g/dL. By way of comparison, the normal hemoglobin level range for adult men is 13 to 18 g/dL and for adult women is 12 to 16 g/dL.

36. In 1991, the FDA expanded epoetin's indications to include treatment of anemia associated with zidovudine therapy in patients with AIDS. In 1993, the FDA expanded the license to include the treatment of anemia associated with cancer chemotherapy. In 1996, the FDA once again expanded the indications for epoetin, this time for treatment in pre-surgical administration to reduce perioperative transfusion requirements.

37. Because of its deal with J&J, Amgen's marketing of Epogen has been limited to dialysis patients in the United States. However, many hospital pharmacies exclusively carry either Epogen or Procrit, not both, and thus the two drugs are often used for purposes for which they are not marketed (although the drug is approved for these uses). Resultantly, Amgen and J&J have a financial agreement on how to compensate each other for these "out of market" sales.

VI. AMGEN'S FRAUD

38. Between 1996 and 2010, Amgen claimed that using epoetin therapy to target hemoglobin levels to above eleven grams per deciliter of whole blood improves the quality of life of dialysis patients as measured by objective criteria known as the Health Related Quality of Life Indicators ("HRQoL"). However, during this entire period Amgen had actual knowledge, based on the results of its own large controlled trial, that using Epogen therapy to target hemoglobin levels to above 11 g/dL of whole blood in dialysis patients with heart disease does not improve the quality of life of dialysis patients with heart diseases as measured by objective criteria, namely, the HRQoL. Between 1996 and 2010, Amgen represented to the medical community, thought leaders, and government formularies, that Epogen improves quality of life even though its own trial

established the opposite with respect to dialysis patients with heart disease targeted above 11 g/dL.

39. Improvements in quality of life are measured using validated questionnaires, and can lead to a drug having a specific indication of improving quality of life by the FDA. Epogen did not have a specific indication for treatment of fatigue, poor vitality, or physical functioning (three domains of quality of life thought to improve with anemia treatment). However, the Epogen label described significant improvements in quality of life, though these improvements were observed when treating patients from severe anemia (hemoglobin < 8g/dL) to values near the then-approved target of 10-12g/dL. The claim that quality of life incrementally improved as hemoglobin was progressively targeted higher with Epogen led physicians to adopt more aggressive treatment plans, and therefore to use substantially more Epogen, including on dialysis patients with heart disease.

40. In 1993, four years after winning FDA approval, Amgen commenced the Normal Hematocrit Trial ("NHT"). Amgen conducted the trial to test the hypothesis that higher hemoglobin levels would reduce mortality, improve survival, and, importantly, improve quality of life as measured by the HRQoL of dialysis patients with heart disease. One secondary endpoint of the study was changes in quality-of-life scores. This trial remains the largest trial of epoetin usage in dialysis patients with heart disease ever conducted.

41. The NHT randomized 1265 hemodialysis patients with cardiac disease to maintain their hemoglobin with epoetin at the standard range (9-11 g/dL) – the "low arm" - or to target a higher range (13-15 g/dL) – the "high arm" - by serial epoetin dose increases, in order to test the hypothesis that higher hemoglobin levels would reduce

mortality, improve survival, and, importantly, improve quality of life as measured by the HRQoL. Patients entered the trial already on epoetin with a stable hemoglobin level at 10-11 g/dL. Because hemoglobin carries oxygen through the body, it was hypothesized higher hemoglobin targets would increase the some aspects of HRQoL, such as the Physical Function component. The patients in the NHT were required to have heart disease and more than 50% of all dialysis patients in the United States have known heart disease.

42. The NHT was an open-label study, meaning investigators, patients, and Amgen knew which arm (lower or higher) each patient had been randomized into. The results of hemoglobin levels on patients' blood samples obtained throughout the study were sent to Amgen. Amgen also knew each patient's epoetin dose, and whether patients were randomized to a standard hemoglobin target of around 10 g/dL or the higher target of around 14 g/dL. Based on the hemoglobin levels, Amgen would make weekly recommendations to each study site on whether to change the epoetin dose and by how much.

43. As the study progressed, and consistent with good clinical trial practices, Amgen was notified within two days which patients sustained serious adverse effects ("SAE") as well as the nature of the SAEs they suffered. Additionally, Amgen had virtually real-time knowledge of which study participants suffered fatal SAEs and which trial arm (high or low) the patients were in. Therefore, Amgen could track the mortality trends in each trial arm. Amgen forwarded these interim trial results to the Data Safety Monitoring Board ("DSMB") on three occasions.

44. In May of 1996, Amgen terminated the NHT based on the recommendation of the DSMB. The DSMB based its recommendation on its interim

analysis of study data through March 31, 1996 - the last analysis DSMB performed - which revealed an increase in deaths and heart attacks in the "high arm" study participants, that is, in the study participants with hemoglobin target levels of 13-15 g/dL.

45. Amgen analyzed the trial results using a pre-specified statistical plan, which is in accordance with good trial practices and FDA requirements. Amgen's analysis showed that, compared to treatment to a standard hemoglobin of 9-11 g/dL, treatment to the higher target of 13-15 g/dL with higher epoetin doses causes an increase in deaths and heart attacks.

46. Critically for the purpose of this action, Amgen's analysis of the data using the pre-specified statistical plan also showed that there was no improvement in quality of life as measured by the HRQoL when targeting hemoglobin to between 13 and 15 g/dL compared when targeting to between 9 and 11 g/dL. There is a direct relationship between higher hemoglobin and higher QoL results up to some level, after which QofL scores plateau. There is no scientific hypothesis that targeting a higher level of hemoglobin could ever yield a decreased QoL result. The comparison between the 9-11 g/dL group and 13-15 g/dL group in the NHT using the pre-specified statistical plan showed no difference between the two groups in terms of QoL results. Thus the NHT established that the QoL scores reach their apex and then plateau at or before the 9-11 g/dL target range for dialysis patients with heart disease.

47. Because there was no improvement of quality of life, Amgen knew that treatment to any hemoglobin target above 11 g/dL had no likelihood of improving quality of life in dialysis patients with heart disease. Amgen knew that the results of such an analysis - if made public - would severely limit the marketability and profitability of Epogen.

48. On August 30, 1996, Amgen submitted the Amgen Clinical Trial Report ("ACTR") to the FDA. The ACTR was not a public document, and was not seen by any of the public until Dr. Coyne obtained a copy of it in 2011. The ACTR included the data from the NHT as well as Amgen's analysis of the data. The ACTR was not made public at the time. The ACTR was based on data from the NHT up to and including the last data set submitted to the DSMB. The ACTR was based on data from the NHT up to and including the last data set submitted to the DSMB covering treatment until March 31, 1996, and also included some analyses of complete trial results through trial termination on June 24, 1996. In the ACTR that Amgen submitted to the FDA, Amgen's analysis of the data used an unusually stringent statistical threshold for significance. Instead of applying the medical standards of $p < 0.05$ and a relative risk (the ratio of events in the high arm versus the low arm) with 95% confidence intervals that do not cross 1.0 (which means there is a less than 1 in 20 chance that a difference in outcome is due to chance), which the study intended to use based on its pre-trial protocols, Amgen employed a $p < 0.00088$ and 99.912% confidence intervals (which means there is less than a .025 chance in 20 that result was due to chance). Amgen justified this because the DSMB had asked the trial to be stopped, and the DSMB was using this very stringent statistical threshold for stopping the trial. Amgen agreed to stopping the study and did so June 24, 1996. Because the DSMB asked the study to be stopped despite not reaching this statistical threshold, Amgen determined the risk of deaths from targeting higher hemoglobin to be insignificant, although the p value was $p = 0.012$ and a relative risk was 1.26 (95% confidence intervals of 1.02 to 1.56).

49. Following the FDA's review of the ACTR, Amgen agreed to an alteration of the Epogen package insert. This alteration to the Epogen package insert showed a

higher proportion of deaths, heart attacks, and thrombotic events in the high arm (the group receiving the higher epoetin doses), but did not state a causal relationship had been established, and did not provide any statistical testing. Therefore, the medical community had to turn to the medical publication of the results to determine if the NHT had shown significant harm.

50. Critically, although the data Amgen submitted to the FDA established that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease, the FDA was reviewing the data only for safety because the drug had already been approved for use. As a result of the FDA's exclusive focus on safety, the FDA was not concerned with the quality of life results, and the revised Epogen label did not report that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease.

51. The FDA accepted that treating severe anemia to the approved range (10-12 g/dL) would improve quality of life. Thus FDA allowed Amgen's Epogen label to read:

> [O]nce the target hematocrit (32% to 38%) was achieved, statistically significant improvements were demonstrated for most quality of life parameters measured, including energy and activity level, functional ability, sleep and eating behavior, health status, satisfaction with health, sex life, well-being, psychological effect, life satisfaction, and happiness. Patients also reported improvement in their disease symptoms. They showed a statistically significant increase in exercise capacity (V02 max), energy, and strength with a significant reduction in aching, dizziness, anxiety, shortness of breath, muscle weakness, and leg cramps. (See the 1999 package insert for Epogen).

52. Amgen's 1999 labeling claims regarding QofL were not based on the results of the ATCR. The labeling claims were based on studies that treated severely

anemic patients to that ranage. In fact, the labeling claims regarding quality of life were made entirely without regard for the NHT results concerning quality of life. The labeling did not specifically address that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease. Despite Amgen's possession of data establishing that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease, Amgen failed to include this fact in the Epogen labeling. Instead, Amgen's label touted the association between quality-of-life benefits and higher hemoglobin levels, but failed to state that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease. Amgen, not FDA, remained at all times responsible for the accuracy of its Epogen labeling. *Wyeth v. Levine*, 555 U.S. 555, 570-71, 129 S. Ct. 1187, 1197-98, 173 L. Ed. 2d 51 (2009) ("it has remained a central premise of federal drug regulation that manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.").

53. While the NHT was ongoing, Amgen made the decision to establish and control guidelines payers and practitioners would use to determine proper use of Epogen. To that end, in 1995 Amgen funded the establishment of a guideline writing organization known as Dialysis Outcomes Quality Initiative ("DOQI") through the National Kidney Foundation ("NKF"). In 1997, DOQI released anemia management guidelines after the NHT had been terminated and Amgen had submitted the ACTR to the FDA, but before the NEJM article - discussed below - was published.

54. Amgen was the founding and principal sponsor of the DOQI guidelines. The 1997 guidelines recommended physicians target hemoglobin to 11-12 g/dL, which is

the upper half of the FDA approved target of 10-12 g/dL. That small difference in target hemoglobin significantly increased the amount of Epogen administered to all dialysis patients, as all patients with hemoglobin of 10-10.9g/dL would undergo Epogen dose increases to achieve the Amgen-funded DOQI recommended target of 11-12 g/dL. As Amgen had already analyzed the NHT results and filed the ACTR with the FDA in 1996, it knew that the NHT had shown dialysis patients with heart disease garnered no benefit from a hemoglobin target above 11g/dL. After issuance of the 1997 DOQI guidelines, Amgen continued to fund additional major guidelines, which recommend more aggressive anemia treatment than indicated in the FDA label.

55. In 1998, two years after Amgen terminated the NHT, the New England Journal of Medicine ("NEJM") published the results of the NHT in an article titled "The Effects of Normal as Compared with Low Hematocrit Values in Patients with Cardiac Disease Who Are Receiving Hemodialysis and Epoetin." The article authors were Anatole Besarab, M.D., W. Kline Bolton, M.D., Jeffrey K. Browne, Ph.D., Joan C. Egrie, Ph.D., Allen R. Nissenson, M.D., Douglas M. Okamoto, Ph.D., Steve J. Schwab, M.D., and David A. Goodkin, M.D. Amgen exercised substantial control over the NEJM article. Of the eight authors of the journal article, four were employees of Amgen and two others had served as consultants to Amgen. Specifically, Amgen employed Browne, Egrie, Okamoto, and Goodkin. At the time of publication of the NEJM article, Drs. Schwab and Nissenson had served as consultants to Amgen, and Dr. Besarab reported an affiliation with Amgen. The corresponding author (this is the most responsible author) was an Amgen employee. The artcles reads in part: "Address reprint requests to Dr. Goodkin at Clinical Research, Amgen, 1 Amgen Center Dr., Thousand Oaks, CA 91320." Amgen employees helped write the initial submission, and this would have been

approved by all the authors prior to submission. Revisions are a product of negotiations between the corresponding author and the NEJM editors. All the authors, including the Amgen employees must approve the final manuscript.

56. The article's authors had full access to the ACTR and all the underlying data from the NHT. Critically for this action, the fact that these authors of the NEJM article had full access to the ACTR and all the underlying data from the NHT means that these authors had actual knowledge that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease as measured by the HRQofL. Despite this knowledge, these authors did not disclose that that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease. To the contrary, the authors reported the NHT results indicated a significant improvement in quality of life. This statement was highly misleading. While the article said there were quality-of-life benefits to higher hematocrit levels, it omitted the fact that no such difference was detected between patients in the higher-dose and lower-dose groups. Instead, while the NEJM article methods section said quality of life would be compared between the two trial groups (the high arm and the low arm), the results reported in the NEJM were a post hoc association of higher achieved hemoglobin to higher quality of life scores at 12 months *within the high target group*. The statement was made more misleading because the article also stated, "There were no significant changes in the scores on the other seven [quality of life] scales," further implying the physical function change was significant. The article did not include the pre-specified quality of life results in the ACTR - which established that there was absolutely no improvement.

57. While the NEJM article authors did not disclose the fact that no difference was detected between patients in the higher-dose and lower-dose groups, they did disclose

other circumstances where there was no significant difference in outcomes between the higher arm and the lower arm. For example, the authors disclosed that there were no significant differences in blood pressure between the two groups during the study. The authors also disclosed there were no significant differences between the groups in the rates of hospitalization for all causes, nonfatal myocardial infarction, angina pectoris requiring hospitalization, congestive heart failure requiring hospitalization, coronary-artery bypass grafting, or percutaneous transluminal coronary angioplasty. The authors' failure to include a similar statement with respect to quality of life results rendered the article's statement that the NHT showed improvement to quality of life even more misleading.

58. Upon publication of the NEJM article in 1998, Amgen knew that neither the FDA nor the NEJM article had informed the medical community that the NHT established that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease. Amgen also knew that approved Epogen label described the alleged quality of life benefits provided by Epogen, yet omitted any reference to the fact that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease. Further, Amgen knew from the NHT results that hemoglobin targets above 13 g/dL were unsafe, and knew it lacked trial data showing hemoglobin targets above 11 g/dL were safe. As a result, Amgen knew that targeting hemoglobin above 11 g/dL in dialysis patients with heart disease offered no significant benefit to patients on dialysis with heart disease (i.e. most dialysis patients). Amgen also knew that only it and the FDA possessed the raw data and pre-defined analyses from the NHT, and also knew that the FDA had no motive to revisit the data or analyze it vis-a-vis quality of life.

59. Amgen continued to conceal the fact that targeting hemoglobin above 11 g/dL in dialysis patients with heart disease offered no significant benefit. By 2001, the Amgen-funded and controlled DOQI guideline organization had changed its name to KDOQI. KDOQI reconfirmed in its 2001 guidelines the hemoglobin goal of 11-12g/dL. These Amgen-controlled guidelines did not disclose that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease.

60. Amgen repeatedly failed to correct the KDOQI guidelines or the Epogen labeling, even though it exercised significant influence over the guideline boards and the labeling for Epogen. The labeling and Amgen-controlled guidelines were relaying material facts that Amgen knew to be false. The NKF aggressively promoted adoption of the new KDOQI guidelines, and Amgen provided published volumes of the guidelines to most, if not all, dialysis centers. Amgen also promoted adoption of the guidelines by dialysis units and chains and established financial incentives to increase the amount of Epogen used each year. The KDOQI guidelines became the most commonly used dosing guidelines for Epogen.

61. In 2001, Besarab, M.D., the primary author of the 1998 NEJM publication of the NHT, continued to promote QoL benefits derived from higher hemoglobin levels obtained as a result of higher Epogen dosages. In the article, Besarab misstated that the NHT trial results regarding improved quality of life based on between group comparisons when in fact they were based on within group comparisons. In the 2001 article, Besarab encouraged hematocrit normalization "in almost all patients," stating the NHT trial showed "significant improvements in QOL parameters in the patients in the normal (hematocrit) group…" Unstated was the fact that the low arm had just as many patients with higher 'physical function' scores. In other words, the NHT

showed that targeting hemoglobin to above 11 g/dL raised no one's quality of life. Besarab was a consultant for Amgen. In subsequent publications, the academic authors of the NEJM article who were on Amgen's payroll continued to misrepresent the results of the NHT.

62. Amgen also helped fund patient advocacy groups, such as American Association of Kidney Patients ("AAKP"), to promote - based largely on associational data - the idea that hemoglobin greater than 11 g/dL was life saving and significantly improved quality of life. Associational data is a far weaker form of evidence than a controlled study like the NHT, and associational data has no persuasive value when contradicted by a controlled study. Amgen, through varied corporations and organizations, independently and through a lobbying group they formed called Kidney Care Partners ("KCP"), aggressively promoted to CMS that maintaining hemoglobin greater than 11 g/dL was a clinical goal because it was associated with better survival and improved quality of life. Amgen (directly, though its lobbyists, and though its lobbying group Kidney Care Partners – which was made up of Amgen, major dialysis chains, and the NKF) persuaded CMS to adopt as a quality care indicator the proportion of patients in a facility of dialysis patients with hemoglobin greater than 11 g/dL. Amgen persuaded CMS to adopt the quality care indicator by omitting and concealing the fact established by the NHT that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease.

63. The overwhelming majority of dialysis patients are covered by Medicare and/or Medicaid. Thus, the federal government became the largest payer for Epogen. When dialysis facilities purchased Epogen, the reimbursements from Medicare (now

CMS) and the incentives from Amgen made Epogen highly profitable and escalating a dialysis facility's Epogen use was even more profitable.

64. Amgen knew that decreasing blood transfusions was not a basis to target hemoglobin to above 11 g/dL in dialysis patients with heart disease. Amgen accepts that hemoglobin above 10 g/dL is sufficient to reduce transfusions in dialysis patients. An Amgen document submitted to the FDA in October 2010 titled "Results of the Trial to Reduce Cardiovascular Events with Aransep® Therapy (TREAT) - Benefits and Risks of Erythropoiesis-Stimulating Agents (ESA) in Patients With Chronic Renal Failure Who Are Not Receiving Dialysis," claims the optimal hemoglobin concentration to reduce transfusion is above 10g/dL, not above 11 g/dL. The report reads in part, "6.3.2.1 A Hemoglobin Concentration of > 10 g/dL Is Optimal to Reduce" and "As demonstrated both in clinical trials and in observational studies, in patients who are receiving dialysis the risk of transfusion increases significantly as the hemoglobin concentration in the preceding month decreases below 10 g/dL; this risk continues to increase as hemoglobin levels decline further…Thus, the goal of transfusion reduction or avoidance is best served by maintaining a hemoglobin concentration above 10 g/dL."

65. Likewise, by 2006, claims that higher hemoglobin could reduce mortality and cardiac events had largely been disproven. This left only the claim of improved quality of life as a reason to treat to higher hemoglobin (and use more Epogen). In 2006, the KDOQI guidelines and other guidelines used HRQoL as the sole measuring basis for recommending higher hemoglobin levels. The 2006 KDOQI guideline read in part, "... *QOL (quality of life) is* a sufficient and, apparently, the sole determinant of treatment benefit." The 2006 guideline did not disclose that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease. The 2006 KDOQI

guidelines increased the target hemoglobin range from 11 to 12 to 11 to 13 g/dl for all patients with chronic kidney disease.

66. The 2006 KDOQI guideline was written by a workgroup that was chaired by David Van Wyck. Allen Nissenson was also a member of the workgroup. At the time, Van Wyck and Nissenson were consultants, and soon to be executives, for DaVita, Epogen's largest user. Van Wyck was a consultant for Amgen and received honoraria payments from Amgen. More broadly, 10 of the 16 members of the workgroup that created the new dosing guidelines reported receiving consulting fees, speaking fees or research funds from Amgen or Johnson & Johnson's subsidiary, Ortho Biotech. In the 2006 KDOQI guidelines, Amgen alone has its name and logo in the front of the journal, and the acknowledgments recognize Amgen alone for supporting the guideline development.The Acknowledgement to the 2006 Guidelines read in part, "The National Kidney Foundation, as well as the Work Group, would like to recognize the support of Amgen for the development of the Guidelines. The National Kidney Foundation is proud to partner with Amgen on this important initiative."

67. To support the guideline statement regarding improved quality of life, KDOQI could point to only five high quality trials even testing the claim that targeting hemoglobin to above 11 g/dL improves QofL. Two of the five had shown no improvement in quality of life. Only one of the five – the NHT - uniquely involved dialysis patients with heart disease. The NHT results were central to the 2006 KDOQI guidelines claim regarding quality of life given its large size (no other trial was even half as large) and that it uniquely treated patients with heart disease. Without Amgen's concealment of the fact that targeting hemoglobin above 11 g/dL does not improve

quality of life in dialysis patients with heart disease, the guideline could not recommend aggressive anemia treatment.

68. Amgen also funded guidelines issued by a group known as Kidney Disease – Improving Global Outcomes ("KDIGO"). KDIGO sought to internationalize the misleading KDOQI guidelines. Amgen excercised signficatnt control over KDIGO. In 2006, KDIGO wrote supportive commentaries for the KDOQI guidelines, which guidelines called for targeting hematocrit at 11-13 g/dL, rather than 11-12. The guidelines did not address the fact that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease.

69. Amgen worked with select anemia experts to conceal the knowledge that the NHT trial had shown that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease, and that the results published in the NEJM were actually nothing more than associational data. Amgen knew clinical guideline groups would not be able to credibly promote the concept that targeting higher hemoglobin improved quality of life if they knew the NHT's randomized trial results showed that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease, and that the NEJM 1998 report was just a post hoc within-group association analysis. Outside anemia experts were unable to question or criticize the guidelines' claims regarding quality of life because they lacked access to the data needed to determine that the claims were false.

70. In addition to exercising complete control over the raw data from NHT proving epoetin does not improve quality of life in dialysis patients with heart disease when targeting hemoglobin above 11 g/dL, Amgen also exercised significant influence over the organizations the medical community and CMS relied on in making prescribing

and purchasing decisions. Amgen secured significant positions of influence regarding anemia guidelines and treatment recommendations, and many of the organizations and individuals involved in the NHT and NEJM article also influenced Epogen prescribing and purchasing decisions. Amgen was contractually linked to Fresenius and DaVita, the two largest kidney care companies in the United States. Amgen and these corporations had a mutual interest in keeping Epogen use high. Allen Nissenson and David Van Wyck, who were members of DaVita's Office of the Chief Medical Officer, had both been involved with the NHT.

71. Amgen did not publish another report on the major NHT trial results to inform and expand on the 1998 NEJM information until 2008. The 2008 publication, a letter, again failed to report the quality of life results. Amgen also never again performed a clinical outcomes trial in dialysis patients with heart disease to assess the safety or efficacy of Epogen to target hemoglobin above 11 g/dL. Thus, Amgen knew that it could continue to aggressively market Epogen as improving quality of life based on the FDA Epogen label, the NEJM publication, the KDOQI guidelines, and other data it disseminated throughout the medical community, so long as it was able to prevent the medical community from seeing the raw data generated in the NHT.

VII. RELATOR'S DISCOVERY OF AMGEN'S MASSIVE FRAUD

72. In 2003, Dr. Coyne gave medical presentations on behalf of Amgen. One such presentation concerning epoetin was entitled "The Changing Face of Anemia in Dialysis Patients." Amgen provided Coyne presentation guidelines, which included notes, references, and statistical information. Amgen was having Coyne promote Epogen to achieve the higher KDOQI hemoglobin target of 11-12 g/dL rather the lower FDA target of 10-12 g/dL. Amgen promoted this for all patients and did not exclude from this

goal dialysis patients with heart diseases, even though Amgen had actual knowledge that that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease. Further, although the marketing materials claimed to be supported by both objective and subjective data, Coyne realized that Amgen made no mention of the NHT results in the presentation, yet repeatedly promoted the "association" of hemoglobin greater than 11 with better clinical outcomes, including better quality of life, and reduced morbidity and mortality. Coyne found it puzzling, in fact illogical, that Amgen would rely on associational data when randomized data from the NHT study should have supported (or refuted) the quality of life claims.

73. In 2004, Coyne performed a statistical test on the NHT mortality results, and noted it showed the p value was significant (p=0.02), yet the trial report and all subsequent renal literature stated the trial showed no significant harm. The close relationships among those who conducted the NHT, those who wrote the NEJM article, DaVita, and KDOQI board members further raised his suspicions about Amgen's quality of life claims.

74. In or around 2006, Coyne discussed his concerns about the association between improved quality of life and targeting hemoglobin to above 11 g/dL in dialysis patients with heart disease with Steven Fishbane. Fishbane was part of the KDOQI workgroup and had also been an investigator in the NHT. Fishbane told Coyne that Fishbane believed the quality of life data Amgen was touting was completely associational, and not based on group comparisons. Even after this communication, KDOQI guideline tables continued to make the claim that the HRQoL improvement was due to randomization to normal hematocrit levels.

75. In a 2007 communication with Dr. Stephen Adler of the New York Medical College, Coyne learned that years earlier Amgen had considered buying dialysis units so it would have a market for Epogen, but that it was advised instead to influence the writing of guidelines such as KDOQI.

76. In 2007, the FDA convened a subcommittee meeting and released a briefing book that, for the first time, showed the unadjusted results for some aspects of the NHT trial. These results demonstrated significant harm occurred when targeting higher hemoglobin levels. That is, these results confirmed Dr. Coyne's suspicions from 2004. FDA did not review or present the NHT quality of life data. Its primary concern was safety.

77. Although the FDA caused Amgen to limit its quality of life claims, Amgen succeeded in keeping enough quality of life language in the-label to permit its fraudulent marketing plan to continue. The changes in 2007 label reflect a change in the general scientific approach of the FDA to measuring changes in QoL. The revised 2007 label read in pertinent part: "Once the target hematocrit (32% to 38%) was achieved, statistically significant improvements were demonstrated for activity level and functional ability, exercise capacity, energy, shortness of breath, and muscle weakness." The revised labeling omitted that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease.

78. Amgen knew all of these claims regarding quality of life claims were false for dialysis patients with heart disease. The results identified on the 2007 label were confirmed in an additional randomized, double blind, placebo-controlled clinical trial in adult dialysis patients. However, this study was based on much healthier and younger patients with severe anemia. The study provided no information regarding improvement

of quality of life of dialysis patients with heart disease when targeting hemoglobin above 11 g/dL. Thus even when Amgen revised its labeling to limit its claims regarding quality of life, it continued to omit the material fact that that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease.

79. Amgen knew that targeting hematocrit to above 11 g/dL in the NHT had not further improved HRQoL in a randomized control trial, one much larger than the additional clinical trial, yet persisted in failing to notify the FDA or the medical community of this fact, even when re-writing the label. Amgen continued to promote Epogen as improving quality of life for certain HRQoL domains, i.e., physical function and exercise tolerance, despite having direct evidence from its own NHT data that these claims were false with respect to dialysis patients with heart disease.

80. In 2007, upon seeing the discrepancies in the briefing book data in comparison to that which was published in the NEJM, and Amgen's continued quality of life promotions, Coyne sought to obtain the original data sets of the NHT. To that end, Coyne spoke to Dwaine Rieves, M.D., Director of the Division of Medical Imaging Products in the FDA Center of Drug Evaluation and Research. During this conversation, Coyne raised his suspicion that Amgen was perpetuating a fraud by stating Epogen improved quality of life when targeted to above 11 g/dL, while omitting that this was not true with respect to dialysis patients with heart disease. Rieves advised Coyne to make a Freedom of Information Act request for the original data from the NHT.

81. In or around 2007, Coyne also contacted Angela Choi, Senior Health Investigative Counsel for the Senate Finance Committee, and told her that he believed Amgen was using anemia experts to continue to promote higher hemoglobin levels and HRQoL benefits all the while knowing that the true data not only did not support these

conclusions but also showed increased morbidity and mortality rates. In his communication with Choi, Coyne included the article written by Anatole Besarab in or around 2001. See surpa ¶ 61. At all times relevant, Besarab was affiliated with Amgen. He was the primary author of the NEJM publication of the NHT. In that article, Besarab continued to promote HRQoL benefits derived from higher hemoglobin levels obtained as a result of higher Epogen dosages without disclosing that the NTH established that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease.

82. This communication from Coyne to Choi was followed up with a phone call that included Coyne, Angela Choi, and Chief Investigative Counsel Emilia DiSanto. During this conversation, which occurred in late 2007, Coyne once again recited his views that the NHT did not establish an improvement in quality of life in dialysis patients with heart disease when targeted to above 11 g/dL, and also reiterated the need for the original data from the NHT.

83. After raising his concerns with government officials, Coyne submitted a FOIA request to the FDA Office of Management Programs on January 26, 2008. The request sought "the Epoetin alfa BLA number (103324) and 'Normal Hematocrit Study Report' that formed the basis for the September 11, 2007 advisory committee discussion." In the FOIA request Coyne explained, "I am requesting the 'Normal Hematocrit Study Report' filed by Amgen with the FDA, likely in 1996 or 1997, and the FDA analysis and comment on the report at that time." Coyne did not receive the information requested through his FOIA request for more than three years.

84. After Coyne submitted the FOIA request, he persistently contacted government officials. In or around 2010, he contacted Senator Claire McCaskill in an

effort to expedite a response to the FOIA request. Within a few weeks of Coyne contacting Senator McCaskill, Coyne received a call back from the FOIA officer for FDA saying that FDA was aware of the request and working on it. During this period Coyne also sent letters to the FDA FOIA Officer to obtain the documents sought in his FOIA request.

85. It appears that during this delay the FDA and CMS were looking into Dr. Coyne's accusations that Amgen was falsely representing quality of life claims Amgen knew to be untrue. On June 16, 2011, one month before Coyne received the response to his FOIA request, CMS released a National Coverage Decision Memo on epoetin which stated that "despite an exhaustive search, we identified no high quality, randomized clinical trials that were of sufficient design, duration, and power to definitely determine that ESAs provided clinical benefits other than increasing hemoglobin, a putative intermediate clinical surrogate in patients with documented erythropoietin-mediated anemia." On June 24, 2011, 1242 days after Coyne submitted the FOIA request, and two weeks before he received a response, the FDA released a safety warning and new label advice for use of epoetin in chronic kidney disease. The FDA withdrew the previous recommended dose and hemoglobin target of 10-12 g/dL. The new label states that there is no known safe dose of epoetin and no proven safe hemoglobin target. It recommends to decrease or stop epoetin if hemoglobin exceeds 11 g/dL. CMS is of the view that based on the revision of the ESA label by the FDA in 2011 that it would not be appropriate to continue encouraging providers to achieve hemoglobin levels above 10 g/dL in all patients.

86. Two weeks after FDA published the new safety information on which CMS relied, Coyne finally received the data he had requested 1260 days earlier. The

data confirmed Coyne's reports of Amgen's fraud. That is, the data proved that between 1996 and at least 2010 - while Amgen had been promoting higher Epogen dosages as improving quality of life - Amgen knew that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease.

87. After reviewing the data, Coyne contacted Dr. Ellis Unger, one of the FDA's main reviewers, in order to confirm that he was correctly interpreting the data. Unger confirmed Coyne was correctly interpreting the data. Unger also noted that as recently as 2010 he had relied on the misleading data Amgen caused to be published in the NEJM in 1998, when reporting that Epogen did, in fact, increase physical functioning and exercise tolerance factors when evaluating HRQoL.

88. In June 2012, Coyne provided to the Attorney General of the United States and the attorneys general and other proper officials of the Government Plaintiffs a disclosure statement summarizing and supported by all known material evidence in accordance with the provisions of 31 U.S.C. § 3730(b)(2) and applicable state law.

89. In sum, the NHT estabslished in 1996 that targeting hemoglobin above 11 g/dL does not improve quality of life in dialysis patients with heart disease. Amgen exerted significant control over, and had complete responsibility for, the Epogen labeling. It also had control over the NEJM article, the DOQI guidelines, the KDOQI guidelines, the KDIGO guidelines, and its own marketing materials. Amgen used this control to promote hemoglobin levels of patients on dialysis with heart disease to above 11g/dL in order to improve quality of life, while actively concealing its actual knowledge that doing so for dialysis with heart disease provided no improvement in quality of life. The fraud cost the Goventment Plaintiffs billions of dollars.

VII. CLAIMS FOR RELIEF

COUNT ONE
False Claims Act
31 U.S.C. § 3729(a)(1)(A)

90. Relator incorporates the preceding paragraphs of this FAC.

91. This is claim by Relator for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733 against Defendant for having knowingly presented, or caused to be presented, a false or fraudulent claim for payment or approval from at least 1996 through at least 2010.

92. Through the acts, omissions, and misrepresentations described herein, Defendant has caused false or fraudulent claims to be presented for payment. Defendant knowingly caused the government to pay for more Epogen than was reasonable and necessary.

93. The government was unaware of the false or fraudulent claims caused by the Defendant, and but for the acts, omissions, and misrepresentations would not have paid for the excessive amount of Epogen.

94. Because of the these false or fraudulent claims the government has been substantially injured and is entitled to treble damages, to be determined at trial, and a civil penalty of not less than $5,500 and not more than $11,000 per false or fraudulent claim.

COUNT TWO
False Claims Act
31 U.S.C. § 3729(a)(1)(B)

95. Relator incorporates paragraphs 1 through 88 of this FAC.

96. This is a claim by Relator for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733 against Defendant for having knowingly made, used, or

caused to be made or used, a false record or statement material to a false or fraudulent claim for payment or approval from at least 1996 through at least 2010.

97. Through the acts, omissions, and misrepresentations described herein, Defendant has knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim. Defendant has made, used, or caused to made or used a variety of false records and/or statements to influence clinical standards and cause the government to pay claims which would not have been paid had the United States Government known of the false representations.

98. Because of the these false or fraudulent claims, the government has been substantially injured and is entitled to treble damages, to be determined at trial, and a civil penalty of not less than $5,500 and not more than $11,000 per false or fraudulent claim.

COUNT THREE
False Claims Act
31 U.S.C. § 3729(a)(1)(G)

99. Relator incorporates paragraphs 1 through 88 of this FAC.

100. This is a claim by Relator for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733 against Defendant for having knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government from at least 1996 through at least 2010.

101. Because of the these false or fraudulent claims the United States Government has been substantially injured and is entitled to treble damages, to be determined at trial, and a civil penalty of not less than $5,500 and not more than $11,000 per false or fraudulent claim.

COUNT FOUR
False Claims Act
31 U.S.C. § 3729(a)(1)(C)

102. Relator incorporates paragraphs 1 through 88 of this FAC.

103. This is claim by Relator for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733 against Defendant for having conspired to commit a violation of subparagraphs (A), (B), and (G) of 31 U.S.C. § 3729(a)(1) from at least 1996 through at least 2010.

104. Because of the these false or fraudulent claims, the United States Government has been substantially injured and is entitled to treble damages, to be determined at trial, and a civil penalty of not less than $5,500 and not more than $11,000 per false or fraudulent claim.

COUNT FIVE
California False Claims Act
Cal Gov't Code §12651(a)(1)-(3)

105. Relator incorporates paragraphs 1 through 88 of this FAC.

106. This is a claim for treble damages and penalties under the California False Claims Act.

107. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

108. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

109. By virtue of the acts described above, Defendant conspired with others to defraud the California by inducing the California State Government to pay or approve false or fraudulent claims.

110. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

111. By reason of the Defendant's acts, the state of California has been damaged in a substantial amount to be determined at trial.

112. The state of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT SIX
Connecticut False Claims Act
Chapter 319v, Sec. 17b-301 et seq.

113. Relator incorporates paragraphs 1 through 88 of this FAC.

114. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut Government for payment or approval.

115. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut Government to approve and pay such false and fraudulent claims.

116. By virtue of the acts described above, Defendant conspired with others to defraud Connecticut by inducing the Connecticut Government to pay or approve false or fraudulent claims.

117. The Connecticut Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

118. By reason of the Defendant's acts, the state of Connecticut has been damaged in a substantial amount to be determined at trial.

119. The state of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT SEVEN
Delaware False Claims Act
6 Del C. §1201(a)(1)-(3)

120. Relator incorporates paragraphs 1 through 88 of this FAC.

121. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

122. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

123. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

124. By virtue of the acts described above, Defendant conspired with others to defraud Delaware by inducing the Delaware State Government to pay or approve false or fraudulent claims.

125. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

126. By reason of the Defendant's acts, the state of Delaware has been damaged in a substantial amount to be determined at trial.

127. The state of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT EIGHT
Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

128. Relator incorporates paragraphs 1 through 88 of this FAC.

129. This is a claim for treble damages and penalties under the Florida False Claims Act.

130. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

131. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

132. By virtue of the acts described above, Defendant conspired with others to defraud Florida by inducing the Florida State Government to pay or approve false or fraudulent claims.

133. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

134. By reason of the Defendant's acts, the state of Florida has been damaged in a substantial amount to be determined at trial.

135. The state of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT NINE
Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

136. Relator incorporates paragraphs 1 through 88 of this FAC.

137. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

138. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

139. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

140. By virtue of the acts described above, Defendant conspired with others to defraud Hawaii by inducing the Hawaii State Government to pay or approve false or fraudulent claims.

141. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

142. By reason of the Defendant's acts, the state of Hawaii has been damaged in a substantial amount to be determined at trial.

143. The state of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TEN
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. §175/3(a)(1)-(3)

144. Relator incorporates paragraphs 1 through 88 of this FAC.

145. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

146. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

147. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

148. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

149. By virtue of the acts described above, Defendant conspired with others to defraud Illinois by inducing the Illinois State Government to pay or approve false or fraudulent claims.

150. By reason of the Defendant' acts, the state of Illinois has been damaged in a substantial amount to be determined at trial.

151. The state of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT ELEVEN
Massachusetts False Claims Act
Mass. Gen. Laws ch. 12 §5B(1)-(3)

152. Relator incorporates paragraphs 1 through 88 of this FAC.

153. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

154. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

155. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

156. By virtue of the acts described above, Defendant conspired with others to defraud Massachusetts by inducing the Massachusetts State Government to pay or approve false or fraudulent claims.

157. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

158. By reason of the Defendant's acts, the state of Massachusetts has been damaged in a substantial amount to be determined at trial.

159. The state of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWELVE
Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a)-(c)

160. Relator incorporates paragraphs 1 through 88 of this FAC.

161. This is a claim for treble damages and penalties under the Nevada False Claims Act.

162. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

163. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

164. By virtue of the acts described above, Defendant conspired with others to defraud Nevada by inducing the Nevada State Government to pay or approve false or fraudulent claims.

165. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

166. By reason of the Defendant's acts, the state of Nevada has been damaged in a substantial amount to be determined at trial.

167. The state of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT THIRTEEN

New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-14-1 et seq., and New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann. §44-9-1 et seq.

168. Relator incorporates paragraphs 1 through 88 of this FAC.

169. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act.

170. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

171. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

172. By virtue of the acts described above, Defendant conspired with others to defraud New Mexico by inducing the New Mexico State Government to pay or approve false or fraudulent claims.

173. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

174. By reason of the Defendant's acts, the state of New Mexico has been damaged in a substantial amount to be determined at trial.

175. The state of New Mexico is entitled to civil penalties for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT FOURTEEN
North Carolina False Claims Act
N.C. Gen. Stat. §§1-605 et seq.

176. Relator incorporates paragraphs 1 through 88 of this FAC.

177. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

178. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

179. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

180. By virtue of the acts described above, Defendant conspired with others to defraud North Carolina by inducing the North Carolina State Government to pay or approve false or fraudulent claims.

181. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

182. By reason of the Defendant's acts, the state of North Carolina has been damaged in a substantial amount to be determined at trial.

183. The state of North Carolina is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT FIFTEEN
Tennessee Medicaid False Claims Act
Tenn. Code Ann. §71-5-182(a)(1)

184. Relator incorporates paragraphs 1 through 88 of this FAC.

185. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

186. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

187. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

188. By virtue of the acts described above, Defendant conspired with others to defraud Tennessee by inducing the Tennessee State Government to pay or approve false or fraudulent claims.

189. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

190. By reason of the Defendant's acts, the state of Tennessee has been damaged in a substantial amount to be determined at trial.

191. The state of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT SIXTEEN
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

192. Relator incorporates paragraphs 1 through 88 of this FAC.

193. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

194. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

195. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

196. By virtue of the acts described above, Defendant conspired with others to defraud Texas by inducing the Texas State Government to pay or approve false or fraudulent claims.

197. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

198. By reason of the Defendant's acts, the state of Texas has been damaged in a substantial amount to be determined at trial.

199. The state of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT SEVENTEEN
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1)-(3)

200. Relator incorporates paragraphs 1 through 88 of this FAC.

201. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

202. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

203. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

204. By virtue of the acts described above, Defendant conspired with others to defraud Virginia by inducing the Virginia State Government to pay or approve false or fraudulent claims.

205. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

206. By reason of the Defendant's acts, the state of Virginia has been damaged in a substantial amount to be determined at trial.

207. The state of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT EIGHTEEN
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.14 (a)(1)-(3), (7)

208. Relator incorporates paragraphs 1 through 88 of this FAC.

209. This is a claim for treble damages and penalties under the District of Columbia False Claims Act.

210. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

211. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

212. By virtue of the acts described above, Defendant conspired with others to defraud the District of Columbia by inducing the District of Columbia Government to pay or approve false or fraudulent claims.

213. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

214. By reason of the Defendant's acts, the District of Columbia has been damaged in a substantial amount to be determined at trial.

215. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT NINETEEN
Georgia False Medicaid Claims Act
O.C.G.A. §§ 49-4-168 et seq.

216. Relator incorporates paragraphs 1 through 88 of this FAC.

217. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

218. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

219. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

220. By virtue of the acts described above, Defendant conspired with others to defraud Georgia by inducing the Georgia State Government to pay or approve false or fraudulent claims.

221. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

222. By reason of the Defendant's acts, the state of Georgia has been damaged in a substantial amount to be determined at trial.

223. The state of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY
Indiana False Claims and Whistleblower Protection Act
I.C. 5-11-5.5

224. Relator incorporates paragraphs 1 through 88 of this FAC.

225. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

226. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

227. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

228. By virtue of the acts described above, Defendant conspired with others to defraud Indiana by inducing the Indiana State Government to pay or approve false or fraudulent claims.

229. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

230. By reason of the Defendant's acts, the state of Indiana has been damaged in a substantial amount to be determined at trial.

231. The state of Indiana is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY-ONE
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §437 et seq.

232. Relator incorporates paragraphs 1 through 88 of this FAC.

233. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

234. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

235. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

236. By virtue of the acts described above, Defendant conspired with others to defraud Louisiana by inducing the Louisiana State Government to pay or approve false or fraudulent claims.

237. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

238. By reason of the Defendant's acts, the state of Louisiana has been damaged in substantial a amount to be determined at trial.

239. The state of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY-TWO
Michigan Medicaid False Claims Act
MCL 400.601-400.613

240. Relator incorporates paragraphs 1 through 88 of this FAC.

241. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

242. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

243. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

244. By virtue of the acts described above, Defendant conspired with others to defraud Michigan by inducing the Michigan State Government to pay or approve false or fraudulent claims.

245. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

246. By reason of the Defendant's acts, the state of Michigan has been damaged in a substantial amount to be determined at trial.

247. The state of Michigan is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY-THREE
New York False Claims Act
N.Y. State Fin. §§ 187 et seq.

248. Relator incorporates paragraphs 1 through 88 of this FAC.

249. This is a claim for treble damages and penalties under the New York State False Claims Act.

250. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

251. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

252. By virtue of the acts described above, Defendant conspired with others to defraud New York by inducing the New York State Government to pay or approve false or fraudulent claims.

253. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

254. By reason of the Defendant's acts, the state of New York has been damaged in a substantial amount to be determined at trial.

255. The state of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY-FOUR
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §167:61-b(I)(a), (b), and (e)

256. Relator incorporates paragraphs 1 through 88 of this FAC.

257. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

258. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

259. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

260. By virtue of the acts described above, Defendant conspired with others to defraud New Hampshire by inducing the New Hampshire State Government to pay or approve false or fraudulent claims.

261. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

262. By reason of the Defendant's acts, the state of New Hampshire has been damaged in a substantial amount to be determined at trial.

263. The state of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY-FIVE
Oklahoma Medicaid False Claims Act
2007 OK. ALS 137

264. Relator incorporates paragraphs 1 through 88 of this FAC.

265. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

266. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

267. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

268. By virtue of the acts described above, Defendant conspired with others to defraud Oklahoma by inducing the Oklahoma State Government to pay or approve false or fraudulent claims.

269. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal conduct.

270. By reason of the Defendant's acts, the state of Oklahoma has been damaged in a substantial amount to be determined at trial.

271. The state of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY-SIX
New Jersey False Claims Act
N.J. Stat. § 2A: 32C-1 et seq.

272. Relator incorporates paragraphs 1 through 88 of this FAC.

273. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

274. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

275. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

276. By virtue of the acts described above, Defendant conspired with others to defraud New Jersey by inducing the New Jersey State Government to pay or approve false or fraudulent claims.

277. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal inducements and/or business practices.

278. By reason of the Defendant's acts, the state of New Jersey has been damaged in a substantial amount to be determined at trial.

279. The state of New Jersey is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY-SEVEN
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1 et seq.

280. Relator incorporates paragraphs 1 through 88 of this FAC.

281. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

282. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

283. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

284. By virtue of the acts described above, Defendant conspired with others to defraud Rhode Island by inducing the Rhode Island State Government to pay or approve false or fraudulent claims.

285. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal inducements and/or business practices.

286. By reason of the Defendant's acts, the state of Rhode Island has been damaged in a substantial amount to be determined at trial.

287. The state of Rhode Island is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY-EIGHT
Wisconsin False Claims For Medical Assistance Act
Wis. Stat §20.931 et seq.

288. Relator incorporates paragraphs 1 through 88 of this FAC.

289. This is a claim for treble damages and penalties under the Wisconsin False Claims for Medical Assistance Act.

290. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

291. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

292. By virtue of the acts described above, Defendant conspired with others to defraud Wisconsin by inducing the Wisconsin State Government to pay or approve false or fraudulent claims.

293. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal inducements and/or business practices.

294. By reason of the Defendant's acts, the state of Wisconsin has been damaged in a substantial amount to be determined at trial.

295. The state of Wisconsin is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT TWENTY-NINE
Montana False Claims Act
Mont. Code Ann. § 17-8-401 et seq.

296. Relator incorporates paragraphs 1 through 88 of this FAC.

297. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann., § 17-8-401 et seq.

298. The Montana False Claims Act, Mont. Code Ann., § 17-8-403 provides for liability for inter alia any person who engages in any or all of the following conduct: (a) knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval; (b) knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity; (c) conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity; . . .(h) as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within a reasonable time after discovery of the false claim.

299. Defendant at all times relevant to this action sold and continues to sell pharmaceuticals in the State of Montana.

300. By virtue of the conduct alleged herein, Defendant knowingly violated each of the above subsections of the Montana False Claims Act by and through its intentional and/or knowing violations of federal and state laws.

301. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of Defendant's illegal conduct, paid for claims that otherwise would not have been allowed.

302. By reason of these improper payments, the Montana Medicaid Program has been damaged in a substantial amount.

303. Relator is a private person with direct and independent knowledge of the allegations in this FAC, who has brought this action pursuant to the Montana False Claims Act.

COUNT THIRTY
Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-1-104 et seq.

304. Relator incorporates paragraphs 1 through 88 of this FAC.

305. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

306. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

307. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to

induce the Colorado State Government to approve and pay such false and fraudulent claims.

308. By virtue of the acts described above, Defendant conspired with others to defraud Colorado by inducing the Colorado State Government to pay or approve false or fraudulent claims.

309. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal inducements and/or business practices.

310. By reason of the Defendant's acts, the state of Colorado has been damaged in a substantial amount to be determined at trial.

311. The state of Colorado is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT THIRTY-ONE
Minnesota False Claims Act
Minn. Stat. § 15C.01 et seq.

312. Relator incorporates paragraphs 1 through 88 of this FAC.

313. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

314. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

315. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to

induce the Minnesota State Government to approve and pay such false and fraudulent claims.

316. By virtue of the acts described above, Defendant conspired with others to defraud Minnesota by inducing the Minnesota State Government to pay or approve false or fraudulent claims.

317. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal inducements and/or business practices.

318. By reason of the Defendant's acts, the state of Minnesota has been damaged in a substantial amount to be determined at trial.

319. The state of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT THIRTY-TWO
Maryland False Health Claims Act of 2010 Subtitle 6, False Claims Against State Health Plans and State Health Programs
§ 2-601 et seq.

320. Relator incorporates paragraphs 1 through 88 of this FAC.

321. This is a claim for treble damages and penalties under the Maryland False Health Claims Act of 2010, Subtitle 6.

322. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

323. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

324. By virtue of the acts described above, Defendant conspired others to violate the Maryland False Health Claims Act of 2010.

325. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal business practices.

326. By reason of the Defendant's acts, the state of Maryland has been damaged in a substantial amount to be determined at trial.

327. The state of Maryland is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT THIRTY-THREE
Iowa Medicaid False Claims Act,
§ 685.1 et seq.

328. Relator incorporates paragraphs 1 through 88 of this FAC.

329. This is a claim for treble damages and penalties under the Iowa Medicaid False Claims Act.

330. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to any employee, officer, or agent of Iowa, or to any contractor grantee or other recipient of Iowa funds for payment or approval.

331. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, to get false claims paid or approved.

332. By virtue of the acts described above, Defendant conspired with each other and others to defraud Iowa by getting false claims allowed or paid.

333. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not be paid but for Defendant's illegal business practices.

334. By reason of the Defendant's acts, the State of Iowa has been damaged in a substantial amount to be determined at trial.

335. The State of Iowa is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant plus treble damages.

COUNT THIRTY-FOUR
Washington Medicaid Fraud False Claims Act
RCWA 74.66.140

336. Relator incorporates paragraphs 1 through 88 of this FAC.

337. This is a claim for treble damages and penalties under the Washington Medicaid Fraud False Claims Act.

338. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to any employee, officer, or agent of Washington, or to any contractor, grantee, or other recipient of Washington funds for payment or approval.

339. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, to get false claims paid or approved.

340. By virtue of the acts described above, Defendant conspired with others to defraud Washington by getting false claims allowed or paid.

341. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid claims that would not have been paid but for Defendant's illegal business practices.

342. By reason of the Defendant's acts, the state of Washington has been damaged in a substantial amount to be determined at trial.

343. The state of Washington is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant plus treble damages.

VIII. PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment in favor of Plaintiffs and against Defendant as follows:

A. On Counts 1 through 4 of the FAC, judgment in favor of the United States and against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

B. On Count 5 of the FAC, judgment in favor of the state of California and against Defendant in an amount equal to three times the amount of damages the state of

California has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §12651(a);

C. On Count 6 of the FAC, judgment in favor of the state of Connecticut and against Defendant in an amount equal to three times the amount of damages the state of Connecticut has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of the Connecticut False Claims Act, Chapter 319v, Sec. 17b-301 et seq.;

D. On Count 7 of the FAC, judgment in favor of the state of Delaware and against Defendant in an amount equal to three times the amount of damages the state of Delaware has sustained because of Defendant's actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

E. On Count 8 of the FAC, judgment in favor of the state of Florida and against Defendant in an amount equal to three times the amount of damages the state of Florida has sustained because of Defendant's actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082;

F. On Count 9 of the FAC, judgment in favor of the state of Hawaii and against Defendant in an amount equal to three times the amount of damages the state of Hawaii has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

G. On Count 10 of the FAC, judgment in favor of the state of Illinois and against Defendant in an amount equal to three times the amount of damages the state of Illinois has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

H. On Count 11 of the FAC, judgment in favor of the state of Massachusetts and against Defendant in an amount equal to three times the amount of damages the state of Massachusetts has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

I. On Count 12 of the FAC, judgment in favor of the state of Nevada and against Defendant in an amount equal to three times the amount of damages the state of Nevada has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

J. On Count 13 of the FAC, judgment in favor of the state of New Mexico and against Defendant in an amount equal to three times the amount of damages the state of New Mexico has sustained because of Defendant's actions, plus civil penalties for each violation of N.M. Stat. Ann. §27-14- 1 et seq. and N.M. Stat. Ann. §44-9-1 et seq.;

K. On Count 14 of the FAC, judgment in favor of the state of Tennessee and against Defendant in an amount equal to three times the amount of damages the state of Tennessee has sustained because of Defendant's actions, plus a civil penalty for each violation of Tenn. Code Ann. §71-5- 182(a);

L. On Count 15 of the FAC, judgment in favor of the state of Texas and against Defendant in an amount equal to three times the amount of damages the state of Texas has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

M. On Count 16 of the FAC, judgment in favor of the state of Virginia and against Defendant in an amount equal to three times the amount of damages the state of Virginia has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a);

N. On Count 17 of the FAC, judgment in favor of Washington, D.C., and against Defendant in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14(a);

O. On Count 18 of the FAC, judgment in favor of the state of Georgia and against Defendant in an amount equal to three times the amount of damages the state of Georgia has sustained because of Defendant's actions, plus a civil penalty of $11,000 for each violation of O.C.G.A §§ 49-4-168 et seq;

P. On Count 19 of the FAC, judgment in favor of the state of Indiana and against Defendant in an amount equal to three times the amount of damages the state of Indiana has sustained because of Defendant's actions, plus civil penalties for each violation of I.C. §5-11-5.5;

Q. On Count 20 of the FAC, judgment in favor of the state of Louisiana and against Defendant in an amount equal to three times the amount of damages the state of Louisiana has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq.;

R. On Count 21 of the FAC, judgment in favor of the state of Michigan and against Defendant in an amount equal to three times the amount of damages the state of Michigan has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of MCL 400.601 et seq.;

S. On Count 22 of the FAC, judgment in favor of the state of New Hampshire and against Defendant in an amount equal to three times the amount of damages the state of New Hampshire has sustained because of Defendant's actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I);

T. On Count 23 of the FAC, judgment in favor of the state of New York and against Defendant in an amount equal to three times the amount of damages the state of New York has sustained because of Defendant's actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. §§ 187 et seq.;

U. On Count 24 of the FAC, judgment in favor of the state of Oklahoma and against Defendant in an amount equal to three times the amount of damages the state of Oklahoma has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of 2007 OK. ALS 137;

V. On Count 25 of the FAC, judgment in favor of the state of New Jersey and against Defendant in an amount equal to three times the amount of damages the state of New Jersey has sustained because of Defendant's actions, plus civil penalties for each violation of N.J. Stat. §2A:32C-1 et seq.;

W. On Count 26 of the FAC, judgment in favor of the state of Rhode Island and against Defendant in an amount equal to three times the amount of damages the state of Rhode Island has sustained because of Defendant's actions, plus civil penalties for each violation of R.I. Gen. Laws §9-1.1-1 et seq.;

X. On Count 27 of the FAC, judgment in favor of the state of Wisconsin and against Defendant in an amount equal to three times the amount of damages the state of Wisconsin has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of the Wis. Stat. §20.931 et seq.;

Y. On Count 28 of the FAC, that this Court enter judgment in favor of the state of North Carolina and against Defendant in an amount equal to three times the amount of damages the state of North Carolina has sustained because of Defendant's actions plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. §§1-605 et seq.;

Z. On Count 29 of the FAC, judgment in favor of the state of Montana and against Defendant in an amount equal to three times the amount of damages the state of Montana has sustained because of the Defendant's actions, plus a civil penalty of $10,000 for each violation of the Montana False Claims Act, Mont. Code Ann., § 17-8-401 et seq.;

AA. On Count 30 of the FAC, that this Court enter judgment in favor of the state of Colorado and against Defendant in an amount equal to three times the amount of damages the state of Colorado has sustained because of the Defendant's actions, plus a civil penalty of $10,000 for each violation of the Colorado Medicaid False Claims Act, Colo. Rev. Stat., § 25.5-1-104 et seq.;

BB. On Count 31 of the FAC, that this Court enter judgment in favor of the state of Minnesota and against Defendant in an amount equal to three times the amount of damages the state of Minnesota has sustained because of the Defendant's actions, plus a civil penalty of $11,000 for each violation of the Minnesota False Claims Act, Minn. Stat. § 15C.01 et seq.;

CC. On Count 32 of the FAC, that this Court enter judgment in favor of the state of Maryland and against Defendant in an amount equal to three times the amount of damages the state of Maryland has sustained because of the Defendant's actions, plus a civil penalty of $11,000 for each violation of the Maryland False Health Claims Act of 2010, Subtitle 6, False Claims Against State Health Plans and State Health Programs, § 2-601 et seq.;

DD. On Count 33 of the FAC, that this Court enter judgment in favor of the state of Iowa and against Defendant in an amount equal to three times the amount of damages the state of Iowa has sustained because of the Defendant's actions, plus a civil penalty of $10,000 for each violation of the Iowa Medicaid False Claims Act, § 685.1 et seq.;

EE. On Count 34 of the FAC, judgment in favor of the state of Washington and against Defendant in an amount equal to three times the amount of damages the state of Washington has sustained because of Defendant's actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of the Washington Medicaid Fraud False Claims Act, RCWA 74.66.140;

FF. That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the Federal False Claims Act;

GG. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

HH. That Relator and Plaintiffs recover such other relief as the Court deems just and proper.

IX. DEMAND FOR A JURY TRIAL

Relator, on behalf of Plaintiffs, demands a jury trial on all claims alleged herein.

Dated: January 5, 2015

Respectfully Submitted,

/s/ Kenneth J. Brennan

The Restaino Law Firm
Lori Siler Restaino; Texas Bar # 24048800
John M. Restaino, Jr., D.P.M., J.D., MPH
283 Columbine St., Suite 169
Denver, CO 80220
(720) 221-0449
LRestaino@restainolawfirm.com
JRestaino@restainolawfirm.com

TorHoerman Law LLC
Tor A. Hoerman
Kenneth J. Brennan (pro hac vice)
234 S. Wabash, 7th Floor
Chicago, IL 60604
(312) 372-4800
thoerman@torhoermanlaw.com
kbrennan@torhoermanlaw.com

CERTIFICATE OF SERVICE

A true and correct copy of the foregoing First Amended Complaint was electronically filed on January 5, 2015 with the United States District Court for the Eastern District of New York. Notice of this filing will be sent via electronic mail to all parties who have entered an appearance by operation of the Court's electronic filing system. Parties may access this filing through the Court's electronic filing system.

/s/ Kenneth J. Brennan